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(H)

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/463,740	06/05/95	VON BORSTEL	R 1331-143

EXAMINER

HM12/0317

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HUNZ	1623	16
ART UNIT		PAPER NUMBER

DATE MAILED: 03/17/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 2-19-99

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 41 and 58-67 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 41 and 58-67 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

–SEE OFFICE ACTION ON THE FOLLOWING PAGES–

08/463,740

★ U.S. GPO: 1998-421-632/40208

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's **second** submission after final filed on 2-19-99 has been entered.

Claims 41 and 58-67 are pending in the case.

All 35 USC statutes not cited in this Office action can be found cited in full in a previous Office action.

Claims 41 and 58 - 67 stand rejected under 35 USC 103 as being unpatentable over von Borstel et al. in view of Chu et al. for the reasons already of record on pages 2 - 3 of the Office action mailed 4-2-96.

The claims are directed to compositions comprising acylated uridine or acylated cytidine and a uridine phosphorylase inhibitor. Von Borstel et al. discloses compositions comprising acylated uridine or cytidine for elevating blood and tissue levels of free uridine for the treatment of a wide variety of diseases. Von Borstel et al. does not mention uridine phosphorylase inhibitors. However, the Chu et al. reference does teach the use of uridine phosphorylase inhibitors to potentiate the chemotherapeutic effect of pyrimidine nucleoside analogs, such as 5-fluorouridine, by preventing the degradation of said nucleoside analog. The examiner emphasizes that the artisan upon seeing the disclosure of Chu et al. concerning the uridine phosphorylase inhibitors would immediately recognize that such inhibitors would, by definition, increase the blood and tissue levels of free uridine by preventing its degradation. Therefore, Von Borstel et al.

and Chu et al. each disclose a different method for elevating the blood and tissue levels of free uridine. Consequently, the person of ordinary skill in the art at the time of the invention would have found it obvious to combine acylated uridine (taught by Von Borstel et al.) with uridine phosphorylase inhibitors (taught by Chu et al.) in order to further elevate the blood and tissue levels of free uridine in order to treat the disorders identified by Von Borstel et al. as responsive to exogenous uridine. Since the availability of uridine is apparently a limiting nutritional factor in cellular repair, then one would reasonably expect that optimizing that concentration of free uridine would enhance cellular repair and replication.

The applicant argues that there is no motivation to combine the two different methods and compounds for increasing blood and tissue uridine disclosed by each reference. This argument has been fully considered but is not deemed persuasive. Von Borstel et al. teaches that the art recognized goal for treating a variety of diseases or disorders is to increase the free uridine concentration in the blood and tissue with a minimum of side effects. Clearly, the reasonable artisan would have every reason to use a combined modality of treatment in order to achieve the highest safe levels of free uridine, and thereby the highest therapeutic benefits.

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.129(a) and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.129(a). Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first

action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kunz, whose telephone number is (703) 308-4623. The examiner can normally be reached on Tuesday through Friday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marion Knode, can be reached on (703) 308-4311. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Gary L. Kunz

GARY L. KUNZ
PRIMARY EXAMINER
GROUP 1200